and fill to volume with sterile distilled water. Using sterile distilled water, further dilute to the reference concentration of 0.06 microgram of candicidin per milliliter (estimated).

(2) *Disintegration time.* Proceed as directed in §436.212 of this chapter, using the method described in paragraph (e)(1) of that section, except use distilled water as the immersion fluid.

(3) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

§449.610c Candicidin vaginal capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Candicidin vaginal capsules are gelatin capsules containing 3 milligrams of candicidin in a suitable and harmless ointment. The candicidin content is satisfactory if it is not less than 90 percent and not more than 150 percent of the number of milligrams of candicidin that it is represented to contain. The moisture content is not more than 0.1 percent. The candicidin used conforms to the requirements of §449.10(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The candicidin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The candicidin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of 20 capsules.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in §436.106 of this chapter, preparing the sample for assay as follows: Remove the tips from two capsules and express the ointment from each capsule into a separatory funnel containing approximately 50 milliliters of *n*- hexane (containing 0.1 percent butylated hydroxyanisole). Wash out the capsules at least two times with 2- to 3-milliliter portions of warm (approximately 50° C) *n*- hexane (containing 0.1 percent butylated hydroxyanisole). Add the washes to the separatory funnel. Shake the sample and *n*- hexane until homogeneous. Add 15 milliliters of dimethylsulfoxide (containing 0.1 percent butylated hydroxyanisole) and shake well. Allow the layers to separate. Remove the bottom layer and repeat the extraction procedure with a second 15-milliliter portion of dimethylsulfoxide (containing 0.1 percent butylated hydroxyanisole). Combine the extractives in a suitable volumetric flask and fill to volume with sterile distilled water. Further dilute an aliquot with sterile distilled water to the reference concentration of 0.06 microgram of candicidin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[39 FR 19134, May 30, 1974, as amended at 40 FR 15089, Apr. 4, 1975]

§449.650 Nystatin vaginal dosage forms.

§449.650a Nystatin vaginal tablets.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin vaginal tablets are tablets composed of nystatin and suitable and harmless diluents, binders, and lubricants. Each tablet contains 100,000 units of nystatin. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain. The loss on drying is not more than 5 percent. The disintegration time is not more than 1 hour. The nystatin used conforms to the standards prescribed therefor by §449.50(a)(1) (i), (iii), (iv), and (v).

(2) *Labeling.* It shall be labeled in accordance with the requirements of §432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for nystatin content, loss on drying, and disintegration time.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 immediate containers of approximately 300 milligrams each.

(*b*) The batch: A minimum of 36 tablets.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of tablets for 3 to 5 minutes in a high-speed glass blender with sufficient dimethylformamide to give a convenient concentration. Dilute an aliquot with sufficient dimethylformamide to give a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute the stock solution with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

(3) *Disintegration time.* Proceed as directed in § 436.212 of this chapter, using the procedure described in paragraph (e)(1) of that section, except use distilled water in lieu of gastric fluid.

[39 FR 19134, May 30, 1974. Redesignated at 43 FR 43458, Sept. 26, 1978]

§ 449.650b Nystatin vaginal suppositories.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin vaginal suppositories contain in each suppository 100,000 units of nystatin in a suitable and harmless water soluble base. Its potency is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of nystatin that it is represented to contain. Its moisture content is not more than 1.5 percent. The nystatin used conforms to the standards prescribed by § 449.50(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(*b*) The batch: A minimum of 30 suppositories.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of suppositories into a high-speed glass blender jar containing sufficient dimethylformamide to give a convenient concentration. Blend for 3 to 5 minutes. Dilute an aliquot with sufficient dimethylformamide to obtain a concentration of 400 units of nystatin per milliliter (estimated). Further dilute an aliquot with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in § 436.201 of this chapter.

[43 FR 43458, Sept. 26, 1978, as amended at 50 FR 19920, May 13, 1985]

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

Subpart A—Bulk Drugs

Subpart B [Reserved]

Subpart C—Injectable Dosage Forms